

DEPARTMENT OF THE TREASURY Bureau of Alcohol, Tobacco and Firearms Washington, D. C. 20226

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TABLE WINES FOUND TO CONTAIN LEAD

Wine Premises Proprietors, Wholesalers, Importers, and Others Concerned:

Purpose. The purpose of this circular is to advise wine premises proprietors, wholesalers, importers, and others concerned that the Federal Food and Drug Administration (FDA) has announced that there may be some risks and potential health effects due to lead in table wines. FDA has advised ATF that they believe available toxicological evidence supports regulatory action against any table wine containing over 300 parts per billion (ppb) lead. FDA also stated that it is willing to advise ATF on a case-by-case basis whether a particular table wine containing more than 300 ppb lead meets the standards for adulteration under the Federal Food, Drug and Cosmetic Act.

Background. In 1989, ATF began testing various beverages for the purpose of determining to what extent, if any, lead is present. Over 600 samples of products, including juices, wines, non-alcoholic malt beverages, wine coolers, and spirits were analyzed. Although the range of lead in the samples was extensive, only 3 of 117 American table wines tested and only 14 of 435 imported table wines tested were found to have over 300 ppb lead.

The FDA is responsible for establishing safe levels of lead in food products, including alcoholic beverages. ATF submitted to FDA the results of the laboratory tests on the products tested for lead content and asked FDA what, if any, health risk was involved with the levels of lead found in such samples.

ATF was advised that FDA's Health Hazard Evaluation Board (HHEB) determined that, because of developmental toxicity phenomena, the fetus is of most concern. FDA included lactating mothers as a concern and stated that the Commissioner of FDA is preparing a public statement that underscores the warning that pregnant and lactating women should avoid the consumption of alcoholic beverages.

A health warning statement alerting pregnant women has been required on all alcoholic beverage containers bottled on or after November 18, 1989, for sale or distribution in the United States. This warning statement specifically states that "According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects." Nearly all table wine sold or distributed in the United States was bottled on or after November 18, 1989, and therefore, contains a health warning statement which, if followed by consumers, sufficiently addresses the potential hazards to the fetus from exposure to both alcohol and lead.

The HHEB further determined that lead levels above 300 ppb may be harmful to consumers and therefore, FDA, upon request, will evaluate such table wines on a case-by-case basis to determine whether they are adulterated under the Federal Food, Drug, and Cosmetic Act. The HHEB specifically confined its deliberations concerning lead to table wine because the HHEB only had adequate data on such wine on which to determine consumer exposure. While there are many classes of wine available to consumers, table wine represents by far the largest percentage of wines consumed. Therefore, while other wines are of concern, any recommended action by FDA, due to the lack of data, will be necessarily confined to table wines. FDA also intends to initiate rulemaking to establish a regulation that would limit lead in table wine.

Enforcement Action By ATF. ATF will begin taking representative samples of American and imported table wines for laboratory analysis to determine the lead content of such wines. FDA has advised ATF that they believe toxicological evidence would support enforcement action against any table wine that contains more than 300 ppb of lead on the grounds that it may be harmful to consumers. ATF will also keep FDA informed of testing results of all alcoholic beverages found to contain lead. If FDA, after rulemaking, takes regulatory action on lead level limitations for alcoholic beverages, ATF will undertake similar rulemaking.

Testing By Proprietors. ATF anticipates that proprietors who produce and bottle American wines and proprietors who import wines will want to test representative samples of their wines to determine the presence of lead and take necessary action to prevent the introduction into commerce of any wine with over 300 ppb lead. If proprietors do not have the laboratory equipment to test their wines for lead and would like to know where such a test can be done, each ATF Area Office has a list with several commercial laboratories that have indicated they can test for lead.

Inquiries. Inquiries concerning this circular should refer to its number and be addressed to: Associate Director (Compliance Operations), Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW, Washington, DC 20226.

Stephen (. Higgins)

Department of The Treasury Bureau of Alcohol, Tobacco and Firearms Wine and Beer Branch, Rm 5000 Washington, DC, 20226

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